DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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7/18/97 RB

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

Certified/Return Receipt Requested

July 15, 1997

WARNING LETTER

Gerald A. Miller, Owner and
Chairman
Continental Laboratories, Inc.
1769 West Armitage
Chicago, IL 60622

Ref.# - 97-KAN-021

Dear Mr. Miller:

During an inspection of your veterinary drug manufacturing facility located at Madrid, Iowa, conducted on June 10 to 18, 1997, our investigators found significant deviations from the Good Manufacturing Practice for Finished Pharmaceutical (Title 21, Code of Federal Regulations, Part 211). Such deviations cause veterinary drugs manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Our inspection found failure to have adequate Standard Operating Procedures (SOP's) covering equipment cleaning and calibration, and failure to validate the equipment cleaning procedure; failure to verify the reliability of raw material certificates of analysis or conduct identity tests; failure to conduct mixing validation on Aloe Heal Veterinary Cream and Tasty Paste to ensure homogenous mixes; failure to have SOP's for the control of microbiological contamination in non-sterile drug products; failure to set finished product potency specifications for Aloe Heal Veterinary Cream, and failure to conduct all finished product tests; failure to conduct stability testing; failure to validate and maintain the deionized water system to assure it is free of microbiological contamination; failure of batch production records to compare actual yield against theoretical yield; failure to conduct annual product reviews; failure to conduct an adequate investigation of a complaint concerning the death of a dog.

At the conclusion of the inspection Form FDA 483, Inspectional Observations, was prepared, issued to and discussed with Mr. David A. Bequeaith, President. A copy is enclosed for your information.

The above is not intended to be an all-inclusive list of violations at your facility. As a manufacturer of veterinary drugs, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. Other portions of this inspection concerning your medical device manufacturing are still under review, and may be reported in a separate document.

Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions may include seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps that are being taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District

Enclosure - Form FDA 483

cc: David A. Bequeaith, President
Continental Laboratories, Inc.
912 South State Street
Madrid, IA 50156

DISTRIBUTION:
Orig. & enclosure: Addressee
Copy: Related Firm
bcc: LF; FF(1910648); HFA-224; HFV-236; HFI-35/DIB(via FOI); HFC-210; HFC-240(GWQAP); CHI-DO(HFR-MW150); DM/RP; Drug Team; RF

CRP:tlw